UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,996	11/21/2003	Ning Wei	KCX-742 (19795)	9086

22827 7590 11/13/2007

DORITY & MANNING, P.A.
POST OFFICE BOX 1449
GREENVILLE, SC 29602-1449

EXAMINER	
DIRAMIO, JACQUELINE A	
ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
11/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/718,996	WEI, NING	
	Examiner	Art Unit	
	Jacqueline DiRamio	1641	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 01 October 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *None*.
   Claim(s) objected to: *None*.
   Claim(s) rejected: *1-9,12 and 13*.
   Claim(s) withdrawn from consideration: *15-36*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

LONG V. LE 10/31/07
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Continuation of 11. does NOT place the application in condition for allowance because: of the reasons presented in the previous office action. In particular, Applicant argues (see p8-9) that the inclusion of the analyte modulating zone (i.e. scavenging zone) of Buck with the method of Brooks et al. would cause analyte from the test sample to remain in the analyte modulating zone, and therefore would effect the accuracy of the determination of the amount of analyte in the method of Brooks et al. However, this argument is not found persuasive. Brooks et al. teach a method of detecting an analyte residing in a test sample, wherein the method comprises 1) a device that comprises a porous membrane that is in fluid communication with test particles (detection probes) and internal control particles (calibration probes), a detection zone containing a capture reagent for the analtye, and a control reaction zone (calibration zone) containing a capture reagent for said internal control particles; 2) contacting the test particles with the sample; 3) allowing said sample and test particles to flow to said detection zone so that said conjugated test particles or complexes thereof bind to said capture reagent and generate a detection signal; 4) allowing said test particles and internal control particles to flow to said control reaction zone so that said internal control particles bind to said capture reagent and generate an internal control signal (calibration signal); and 5) comparing the intensity of the detection signal to the intensity of the control signal, the quantity of analtye within the test sample being proportional to the intensity of the detection signal calibrated by the intensity of the calibration signal (see column 1, lines 28-67; column 2, lines 1-37; column 3, lines 37-63; column 5, lines 61-67; column 6, lines 1-56; column 7, lines 1-67; column 8, lines 1-4; column 9, lines 43-67; and column 10, lines 1-10). However, Brooks et al. fail to teach that the device includes a scavenging zone that contains a capture reagent for the analyte, wherein the sample is contacted with the scavenging zone prior to contact with the particles, and a predefined base quantity of analyte binds to the capture reagent of the scavenging zone. Therefore, the secondary reference of Buck was combined with Brooks et al. in order to remedy this deficiency because Buck teaches the benefit of including an analyte modulating zone (i.e. scavenging zone) within a lateral flow test strip device in order to bind to a predetermined amount of analyte, prior to contact of the sample with a conjugate zone that contains a reagent for the analyte of interest (i.e.detection particle), which increases the detectable range of analyte concentration, particularly in test samples with high analyte concentration (see Figure 1; column 2, lines 35-52; and column 5, lines 16-34). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the method of Brooks et al. the analyte modulating zone of Buck because Buck teaches the benefit of including an analyte modulating zone within a test strip in order to remove a fraction of analyte from a test sample prior to the sample reaching a conjugate zone and/or analyte test zone to thereby increase the detectable range of analyte, particularly in test samples with high analyte concentration. Further, Buck teaches that the fraction of analyte that is removed in the analyte modulating zone is empirically established during manufacturing and quality control procedures for the lateral flow device (see column 5, lines 16-34). Therefore, when preparing an analyte modulating zone on a lateral flow device, one skilled in the art would determine the amount or fraction of analyte that would be captured by the zone as taught by Buck. Thus, it would be obvious to one of ordinary skill in the art at the time the invention was made to utilize this amount of analyte that is captured in the analyte modulating zone when determining the total amount of analtye in the test sample of Brooks et al. and this would further be utilized when preparing the standard curves. Therefore, Applicant's independent claim 1 is considered obvious over Brooks et al. in view of Buck.